Informed Consent, Capacity Assessment, and Advance Planning in Treatment and Research

Haberstroh, Julia ; Gather, Jakov ; Trachsel, Manuel

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Editorial: Informed Consent, Capacity Assessment, and Advance Planning in Treatment and Research

Julia Haberstroh, PhD[1,2]

Jakov Gather, MD, MA[3,4]

Manuel Trachsel, MD, PhD[5]

[1] Interdisciplinary Ageing Research, Faculty of Educational Sciences, Goethe University Frankfurt am Main, Germany

[2] Institute of General Practice, Department of Medicine, Goethe University Frankfurt am Main, Germany

[3] Institute for Medical Ethics and History of Medicine, Ruhr University Bochum, Germany

[4] Department of Psychiatry, Psychotherapy and Preventive Medicine, LWL University Hospital, Ruhr University Bochum, Germany

[5] Institute of Biomedical Ethics and History of Medicine, University of Zurich, Switzerland

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Correspondence details: J.Haberstroh@em.uni-frankfurt.de

In most jurisdictions, it is a widely accepted ethical and legal requirement that clinicians and researchers must obtain informed consent before conducting a clinical or research intervention. Like any other adult person, old and very old people with or without a mental disorder have the fundamental right to decide whether to accept proposed medically indicated treatment, or to participate in research. However, to exercise this right they must be sufficiently informed, have decision-making capacity, and exhibit voluntariness in reaching a decision (Beauchamp, 2011).

Many questions concerning the informed consent process, and the possibility to plan medical treatments or participate in clinical research in advance, must be resolved to enable people to prepare for the risk of substantially impaired decision-making capacity in the future. How should decision-making capacity be assessed in clinical and research practice? How can clinicians or researchers deal with persons who lack decision-making capacity in a way that is compatible with attaching importance to autonomy, while taking into consideration continuously developing international, and national laws and their challenging practical implementations (e.g., UN-Convention on the Rights of Persons with Disabilities (CRPD); the fourth amendment of the German Medicinal Products Act (AMG))? In current national and international debates, the opportunities provided by advance directives, and the means for their improvement through the likes of advance care planning and research planning, are of crucial significance.

There is no doubt that such debates should be multi- and interdisciplinary and take advantage of scientific and practical expertise. Improvements in the informed consent process and advance planning will particularly benefit geriatric patients because of the high prevalence of both cognitive deficits and (chronic) illnesses, and the frequent need for treatment decisions, in this group of patients. .

This special issue aims to contribute to multi- and interdisciplinary, scientific and practical debates on informed consent and advance planning. The emphasis lies on challenges in the assessment of decision-making capacity in clinical practice, and on the chances and difficulties of advance planning of research and treatment decisions. The four contributions include conceptual, quantitative and qualitative empirical papers.

The first contribution in this issue presents findings from a survey study on knowledge, attitudes, and the evaluation of decision-making capacity among general practitioners and psychiatrists in Croatia. Novosel, Marušić, Biller-Andorno, and Trachsel report that almost all participants indicated they would welcome official guidelines and training because of perceived qualification deficits. The results are similar to outcomes from studies conducted in various other countries and may influence future policy-making processes.

In the second contribution, Iseli, Wangmo, Hermann, Trachsel, and Elger present a qualitative approach to analyzing semi-structured interviews with healthcare professionals from Switzerland. The authors found that three factors made the evaluation of decision-making capacity difficult for clinicians in their daily work: patient characteristics, differing opinions and the consequences of decision-making capacity evaluations, and familial and legal issues affecting the evaluation process.

The third contribution studies decision-making capacity and advance research directives from a conceptual point of view. Against the background of the international legal and ethical framework for biomedical research and particularly the fourth amendment of the German Medicinal Products Act (AMG), Scholten, Gieselmann, Gather, and Vollmann explore the implementation of advance research directives in the context of non-therapeutic research in incompetent populations.

The contribution of Wicki in this issue focuses on decision-making capacity in advance care planning for people with intellectual disabilities. The author provides and tests a new instrument for the evaluation of decision-making capacity in persons with intellectual disabilities - an important and timely contribution in a widely neglected area of research.

The final section of this special issue combines the results of the four multi- and interdisciplinary contributions and draws the conclusion that the normative and empirical sciences should focus more strongly on providing practitioners with the chance to follow and contribute to further developments in the dynamically changing national, and international regulatory environment. There is plenty of work to do before advances in normative conceptualizations find their way into sound empirical studies and implementation concepts and ultimately into clinical, and research practice.

References

Beauchamp, T.L. (2011). Informed consent: Its history, meaning, and present challenges. *Cambridge Quarterly of Healthcare Ethics, 20*, 515-523.